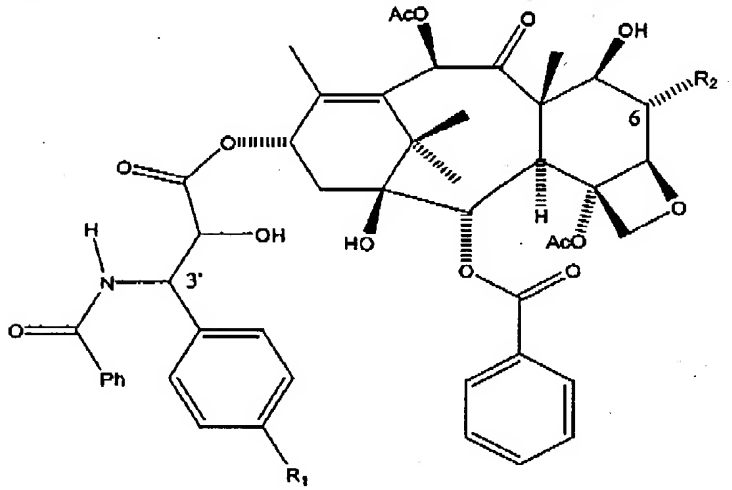
Application No.: 10/800,990 Docket No.: BAKER 3.0-002 CIP DIV CONT CONT

**IN THE CLAIMS**

1. (original) A method of increasing the bioavailability upon oral administration to a human patient of a taxane, comprising orally co-administering to the human patient a taxane and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor, wherein the oral bioavailability enhancing agent is administered substantially simultaneously with administration of the taxane, prior to administration of the taxane, or both prior to and substantially simultaneously with administration of the taxane.

2. (original) The method of claim 1, wherein the taxane comprises a metabolite of paclitaxel.

3. (original) The method of claim 2, wherein the metabolite of paclitaxel is represented by the formula:




wherein $R_1$ represents hydrogen or hydroxyl and $R_2$ represents hydrogen or hydroxyl, provided that when $R_1$ represents hydrogen, $R_2$ represents hydroxyl.

4. (original) The method of claim 1, wherein the taxane is a prodrug of paclitaxel or docetaxel.

5. (original) The method of claim 1, wherein the taxane is a derivative of paclitaxel or docetaxel.

6. (original) The method of claim 1, wherein the enhancing agent is administered either

a) about 0.5-24 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-24 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after, the administration of the taxane.

7. (original) The method of claim 1, wherein the taxane and the enhancing agent are administered in separate oral dosage forms.

8. (original) The method of claim 1, wherein the taxane and the enhancing agent are administered together in a combination oral dosage form.

9. (original) The method of claim 1, wherein the enhancing agent is administered in an amount of about 0.1 to 15 mg/kg of patient body weight.

10. (original) The method of claim 1, wherein the taxane and the enhancing agent are orally co-administered to the patient once a week.

11. (original) The method of claim 1, wherein two or more doses of the taxane are orally administered after a single dose of the enhancing agent.

12. (original) The method of claim 1, wherein the human patient is administered about 20-1,000 mg/m$^2$ of the taxane based on patient body surface area.

13. (original) The method of claim 1, wherein the human patient is administered about 2-30 mg/kg of the taxane based on patient body weight.

14. (original) The method of claim 1, wherein the taxane, the enhancing agent, or both is each administered in a dosage form selected from the group consisting of tablets, capsules, caplets, pills, lozenges, liquid solutions, suspensions and

elixirs.

15. (original) The method of claim 1, wherein the taxane is administered in a formulation further comprising a polyethoxylated castor oil, alcohol or polyoxyethylated sorbitan mono-oleate.

16. (original) A method of increasing the bioavailability upon oral administration to a human patient of paclitaxel, comprising orally co-administering to the human patient paclitaxel and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor, wherein the oral bioavailability enhancing agent is administered substantially simultaneously with administration of paclitaxel, prior to administration of paclitaxel, or both prior to and substantially simultaneously with administration of paclitaxel.

17. (original) The method of claim 16, wherein the enhancing agent is administered either

a) about 0.5-24 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-24 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after, the administration of paclitaxel.

18. (original) The method of claim 16, wherein paclitaxel and the enhancing agent are administered in separate oral dosage forms.

19. (original) The method of claim 16, wherein paclitaxel and the enhancing agent are administered together in a combination oral dosage form.

20. (original) The method of claim 16, wherein the enhancing agent is administered in an amount of about 0.1 to 15 mg/kg of patient body weight.

21. (original) The method of claim 16, wherein paclitaxel and the enhancing agent are orally co-administered to the

patient once a week.

22. (original) The method of claim 16, wherein two or more doses of paclitaxel are orally administered after a single dose of the enhancing agent.

23. (original) The method of claim 16, wherein the human patient is administered about 20-1,000 $mg/m^2$ of paclitaxel based on patient body surface area.

24. (original) The method of claim 16, wherein the human patient is administered about 2-30 mg/kg of paclitaxel based on patient body weight.

25. (original) The method of claim 16, wherein paclitaxel, the enhancing agent, or both is each administered in a dosage form selected from the group consisting of tablets, capsules, caplets, pills, lozenges, liquid solutions, suspensions and elixirs.

26. (original) The method of claim 16, wherein paclitaxel is administered in a formulation further comprising a polyethoxylated castor oil, alcohol or polyoxyethylated sorbitan mono-oleate.

27. (original) A method of increasing the bioavailability upon oral administration to a human patient of docetaxel, comprising orally co-administering to the human patient docetaxel and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor, wherein the oral bioavailability enhancing agent is administered substantially simultaneously with administration of docetaxel, prior to administration of docetaxel, or both prior to and substantially simultaneously with administration of docetaxel.

28. (original) The method of claim 27, wherein the enhancing agent is administered either

a) about 0.5-24 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-24 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after, the administration of docetaxel.

29. (original) The method of claim 27, wherein docetaxel and the enhancing agent are administered in separate oral dosage forms.

30. (original) The method of claim 27, wherein docetaxel and the enhancing agent are administered together in a combination oral dosage form.

31. (original) The method of claim 27, wherein the enhancing agent is administered in an amount of about 0.1 to 15 mg/kg of patient body weight.

32. (original) The method of claim 27, wherein docetaxel and the enhancing agent are orally co-administered to the patient once a week.

33. (original) The method of claim 27, wherein two or more doses of docetaxel are orally administered after a single dose of the enhancing agent.

34. (original) The method of claim 27, wherein the human patient is administered about 20-1,000 mg/m$^2$ of docetaxel based on patient body surface area.

35. (original) The method of claim 27, wherein the human patient is administered about 2-30 mg/kg of docetaxel based on patient body weight.

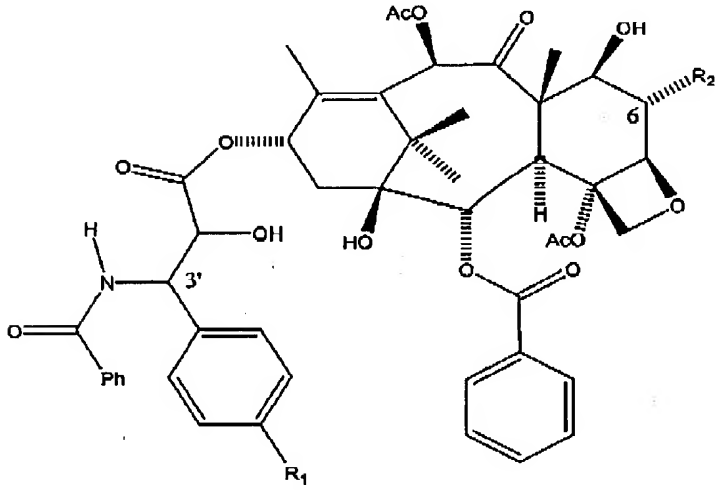
36. (original) The method of claim 27, wherein docetaxel, the enhancing agent, or both is each administered in a dosage form selected from the group consisting of tablets, capsules, caplets, pills, lozenges, liquid solutions, suspensions and elixirs.

37. (original) The method of claim 27, wherein docetaxel is administered in a formulation further comprising a polyethoxylated castor oil, alcohol or polyoxyethylated sorbitan mono-oleate.

38. (original) A method of treating a human afflicted with a disease responsive to a taxane, comprising orally co-administering to the human a taxane and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor.

39. (original) The method of claim 38, wherein the taxane comprises a metabolite of paclitaxel.

40. (original) The method of claim 39, wherein the metabolite of paclitaxel is represented by the formula:




wherein $R_1$ represents hydrogen or hydroxyl and $R_2$ represents hydrogen or hydroxyl, provided that when $R_1$ represents hydrogen, $R_2$ represents hydroxyl.

41. (original) The method of claim 38, wherein the taxane is a prodrug of paclitaxel or docetaxel.

42. (original) The method of claim 38, wherein the taxane is a derivative of paclitaxel or docetaxel.

43. (original) The method of claim 38, wherein the enhancing agent is administered either

a) about 0.5-24 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-24 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after, the administration of the taxane.

44. (original) The method of claim 38, wherein the taxane and the enhancing agent are administered in separate oral dosage forms.

45. (original) The method of claim 38, wherein the taxane and the enhancing agent are administered together in a combination oral dosage form.

46. (original) The method of claim 38, wherein the enhancing agent is administered in an amount of about 0.1 to 15 mg/kg of body weight.

47. (original) The method of claim 38, wherein the taxane and the enhancing agent are orally co-administered to the patient once a week.

48. (original) The method of claim 38, wherein the taxane is administered in a divided dose.

49. (original) The method of claim 38, wherein two or more doses of the taxane are administered after a single dose of the enhancing agent.

50. (original) The method of claim 38, wherein the human is administered about 20-1,000 $mg/m^2$ of the taxane based on patient body surface area.

51. (original) The method of claim 38, wherein the human is administered about 2-30 mg/kg of the taxane based on body weight.

52. (original) The method of claim 38, wherein the taxane, the enhancing agent, or both is each administered in a dosage form selected from the group consisting of tablets, capsules, caplets, pills, lozenges, liquid solutions, suspensions and elixirs.

53. (original) The method of claim 38, wherein the taxane is administered in a formulation further comprising a

polyethoxylated castor oil, alcohol or polyoxyethylated sorbitan mono-oleate.

54. (original) The method of claim 38, wherein the disease is selected from the group consisting of ovarian cancer, pancreatic cancer, breast cancer, lung camcer, germ cell cancer, head and neck carcinomas, hepatocellular carcinoma, liver metastases, genito-urinary and gastrointestinal tract cancers, Kaposi's sarcoma, polycystic kidney disease and malaria.

55. (original) The method of claim 38, wherein the disease is selected from the group consisting of breast cancer, ovarian cancer, gastrointestinal tract cancer, and lung cancers.

56. (original) A method of treating a human afflicted with a disease responsive to paclitaxel, comprising orally co-administering to the human paclitaxel and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor.

57. (original) The method of claim 56, wherein the enhancing agent is administered either

a) about 0.5-24 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-24 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after, the administration of paclitaxel.

58. (original) The method of claim 56, wherein paclitaxel and the enhancing agent are administered in separate oral dosage forms.

59. (original) The method of claim 56, wherein paclitaxel and the enhancing agent are administered together in a combination oral dosage form.

60. (original) The method of claim 56, wherein the enhancing agent is administered in an amount of about 0.1 to 15 mg/kg of body weight.

61. (original) The method of claim 56, wherein paclitaxel and the enhancing agent are orally co-administered to the patient once a week.

62. (original) The method of claim 56, wherein paclitaxel is administered in a divided dose.

63. (original) The method of claim 56, wherein two or more doses of paclitaxel are administered after a single dose of the enhancing agent.

64. (original) The method of claim 56, wherein the human is administered about 20-1,000 mg/m$^2$ of paclitaxel based on body surface area.

65. (original) The method of claim 56, wherein the human is administered about 2-30 mg/kg of paclitaxel based on body weight.

66. (original) The method of claim 56, wherein paclitaxel, the enhancing agent, or both is each administered in a dosage form selected from the group consisting of tablets, capsules, caplets, pills, lozenges, liquid solutions, suspensions and elixirs.

67. (original) The method of claim 56, wherein paclitaxel is administered in a formulation further comprising a polyethoxylated castor oil, alcohol or polyoxyethylated sorbitan mono-oleate.

68. (original) The method of claim 56, wherein the disease is selected from the group consisting of ovarian cancer, pancreatic cancer, breast cancer, lung cancer, germ cell cancer, head and neck carcinomas, hepatocellular carcinoma, liver metastases, genito-urinary and gastrointestinal tract cancers, Kaposi's sarcoma, polycystic kidney disease and malaria.

69. (original) The method of claim 56, wherein the disease is selected from the group consisting of breast cancer, ovarian cancer, gastrointestinal tract cancer, and lung cancers.

70. (original) A method of treating a human afflicted

with a disease responsive to docetaxel, comprising orally co-administering to the human docetaxel and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor.

71. (original) The method of claim 70, wherein the enhancing agent is administered either

a) about 0.5-24 hrs. before,

b) less than 0.5 hr. before, together with or less than 0.5 hr. after, or

c) both about 0.5-24 hrs. before and again less than 0.5 hr. before, together with or less than 0.5 hr. after, the administration of docetaxel.

72. (original) The method of claim 70, wherein docetaxel and the enhancing agent are administered in separate oral dosage forms.

73. (original) The method of claim 70, wherein docetaxel and the enhancing agent are administered together in a combination oral dosage form.

74. (original) The method of claim 70, wherein the enhancing agent is administered in an amount of about 0.1 to 15 mg/kg of body weight.

75. (original) The method of claim 70, wherein docetaxel and the enhancing agent are orally co-administered to the patient once a week.

76. (original) The method of claim 70, wherein docetaxel is administered in a divided dose.

77. (original) The method of claim 70, wherein two or more doses of docetaxel are administered after a single dose of the enhancing agent.

78. (original) The method of claim 70, wherein the human is administered about 20-1,000 mg/m$^2$ of docetaxel based on body surface area.

79. (original) The method of claim 70, wherein the human

is administered about 2-30 mg/kg of docetaxel based on body weight.

80. (original) The method of claim 70, wherein docetaxel, the enhancing agent, or both is each administered in a dosage form selected from the group consisting of tablets, capsules, caplets, pills, lozenges, liquid solutions, suspensions and elixirs.

81. (original) The method of claim 70, wherein docetaxel is administered in a formulation further comprising a polyethoxylated castor oil, alcohol or polyoxyethylated sorbitan mono-oleate.

82. (original) The method of claim 70, wherein the disease is selected from the group consisting of ovarian cancer, pancreatic cancer, breast cancer, lung cancer, germ cell cancer, head and neck carcinomas, hepatocellular carcinoma, liver metastases, genito-urinary and gastrointestinal tract cancers, Kaposi's sarcoma, polycystic kidney disease and malaria.

83. (original) The method of claim 70, wherein the disease is selected from the group consisting of breast cancer, ovarian cancer, gastrointestinal tract cancer, and lung cancers.

84. (original) An oral pharmaceutical dosage form comprising a taxane which is paclitaxel or docetaxel, and an oral bioavailability-enhancing agent comprising a p-glycoprotein inhibitor.

85. (original) The dosage form of claim 84, wherein the taxane comprises docetaxel.

86. (original) The dosage form of claim 84, wherein the taxane comprises paclitaxel.

87. (original) The dosage form of claim 84, which contains about 20-1,000 mg/m$^2$ of the taxane based on average or median patient body surface area.

88. (original) The dosage form of claim 84, which contains about 2-30 mg/kg of the taxane based on patient body

weight.

89. (original) The dosage form of claim 84, further comprising a pharmaceutically inert excipient vehicle, filler, binder, disintegrant, solvent, solubilizing agent, sweetener or coloring agent.

90. (original) The dosage form of claim 84, further comprising a polyethoxylated castor oil, alcohol or a polyoxyethylated sorbitan mono-oleate.

91. (original) The dosage form of claim 84, which is in the form of a tablet or capsule.

92. (original) A kit comprising an oral dosage form containing an oral bioavailability enhancing agent comprising a p-glycoprotein inhibitor, and an oral dosage form containing a taxane which is paclitaxel or docetaxel, or a combination oral dosage form containing both the enhancing agent and the taxane.

93. (original) The kit of claim 92. further comprising an insert containing printed dosing information for the oral co-administration of the enhancing agent and the taxane.

94. (original) The kit of claim 92, wherein the enhancing agent and the taxane are contained in separate oral pharmaceutical dosage forms.

95. (original) The kit of claim 92, wherein the taxane is paclitaxel.

96. (original) The kit of claim 92, wherein the taxane is docetaxel.

97. (new) The method of claim 1, wherein the oral bioavailability enhancing agent comprises MS-209.

98 (new) The method of claim 16, wherein the oral bioavailability enhancing agent comprises MS-209.

99. (new) The method of claim 27, wherein the oral bioavailability enhancing agent comprises MS-209.

100. (new) The method of claim 38, wherein the oral bioavailability enhancing agent comprises MS-209.

101. (new) The oral pharmaceutical dosage form of claim 84, wherein the oral bioavailability enhancing agent comprises MS-209.

102. (new) The oral pharmaceutical dosage form of claim 85, wherein the oral bioavailability enhancing agent comprises MS-209.

103. (new) The oral pharmaceutical dosage form of claim 86, wherein the oral bioavailability enhancing agent comprises MS-209.

104. (new) The kit of claim 92, wherein the oral bioavailability enhancing agent comprises MS-209.

105. (new) The kit of claim 95, wherein the oral bioavailability enhancing agent comprises MS-209.

106. (new) The kit of claim 96, wherein the oral bioavailability enhancing agent comprises MS-209.